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10/586,785	03/16/2007	Thomas Rothmann	QGN-048.1P US	1799
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Leon R. Yankwich			ETHERTON, BRADLEY	
YANKWICH & ASSOCIATES				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/586,785 Examiner BRADLEY ETHERTON	ROTHMANN ET AL. Art Unit 4171

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 7/21/2006.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-24 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 11/9/2006.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

1. This is a first action on the merits of the application.
2. Claims 1 through 23 are pending.

Priority

3. Acknowledgement is made that this application is the U.S. National Phase under 35 USC 371 of International Application PCT/EP2005/000650 filed on January 24, 2005, which claims priority to European Patent Application 04001498.7 filed on January 23, 2004.
4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Copies of the certified copy have been filed.

Specification

5. The disclosure is objected to because of the following informalities: The specification contains references (page 4, lines 26 and 27; page 5, line 1; page 16, line 3) to "silicon oil" which appears to be a misspelling of "silicone oil". Appropriate correction is required.
6. Page 8, line 26 appears to include the German preposition "von" which should be translated. Appropriate correction is required.
7. The claims are not the object of a sentence starting with "I (or we) claim," or "The invention claimed is" or some equivalent. See MPEP 608.01(m). Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-7, 9-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloch, et. al., (U.S. 5,411,876), hereinafter BLOCH as evidenced by Wolfmeier, et. al., ("Waxes" in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH, published on-line June 15, 2000), hereinafter WOLFMEIER.

10. In regard to Claim 1, BLOCH discloses a barrier (col. 4, line 46) for aqueous solutions (col. 9, line 8) in an open or automated system (col. 10, lines 24-26) comprising at least one water immiscible hydrocarbon or hydrocarbon mixture (col. 11, lines 5-26). BLOCH discloses that the barrier is a contamination barrier which prevents contamination of the aqueous solution (col. 8, lines 37-41).

11. The contamination barrier disclosed by BLOCH is a layer of grease or wax (col. 4, lines 46-53) or mineral oil (col. 12, line 28) to seal an aqueous solution in a PCR tube. It is well known in the art that waxes are hydrocarbon mixtures. For example, WOLFMEIER teaches that paraffin waxes are typically composed of straight chain alkanes mixed with weakly branched isoparaffins and monocyclic alkanes (naphthenes) (Sec. 4.2.1., page 25). BLOCH discloses that mineral oil is a hydrocarbon mixture (col. 11, lines 7-10).

12. In regard to claim 2, BLOCH discloses that the barrier is comprised of an unsubstituted hydrocarbon (col. 11, lines 24-26). Both eicosane ($C_{20}H_{42}$) and octacosane ($C_{28}H_{58}$) are unsubstituted hydrocarbons. Furthermore, WOLFMEIER teaches that paraffin waxes are typically composed of straight chain alkanes which are unsubstituted hydrocarbons (Sec. 4.2.1., page 25).
13. In regard to claim 3, BLOCH discloses that the barrier is comprised of a substituted hydrocarbon (col. 11, lines 26-28). Cetyl palmitate ($C_{32}H_{64}O_2$) and pentaerythritol tetrabehenate ($C_{93}H_{180}O_8$) are both hydrocarbons substituted with ester groups. Furthermore, WOLFMEIER discloses that many natural waxes are composed of hydrocarbons substituted with other ester groups, substituted with hydroxyl groups, or substituted with carboxylic acid groups (sec. 2.1, pages 9 and 12).
14. In regard to claim 4, BLOCH discloses that the barrier is comprised of a saturated or unsaturated cyclic hydrocarbon. It is well known in the art that waxes are comprised of mixtures of non-cyclic and cyclic hydrocarbons. For example, WOLFMEIER discloses that paraffin waxes may contain 30 to 60% of isoparaffins and cycloparaffins. (Sec. 4.2.1., page 25).
15. In regard to claim 5, BLOCH discloses that the barrier is comprised of a branched or unbranched acyclic hydrocarbon. It is well known in the art that waxes are comprised of mixtures of branched or unbranched acyclic hydrocarbon. For example, WOLFMEIER discloses that paraffin waxes may contain 30 to 60% of isoparaffins, which are branched acyclic hydrocarbons, and cycloparaffins (Sec. 4.2.1., page 25). As discussed in regard to claim 1, WOLFMEIER teaches that paraffin waxes are typically

composed of straight chain alkanes, which are unbranched acyclic hydrocarbons, mixed with weakly branched isoparaffins, which are branched acyclic hydrocarbons, and monocyclic alkanes (naphthenes) (Sec. 4.2.1., page 25).

16. In regard to claim 6, BLOCH discloses that the barrier is comprised of from 5 to 20 carbon atoms (col. 11, lines 24-26). Eicosane ($C_{20}H_{42}$) is a hydrocarbon comprised of 20 carbon atoms. Furthermore, WOLFMEIER teaches that paraffin waxes, according to the European Wax Federation, are typically composed of straight chain alkanes which contain 18 to 45 carbon atoms. (Sec. 4.2.1., page 25).

17. In regard to claim 7, BLOCH discloses that the barrier is comprised of a branched or unbranched alkane (col. 11, lines 24-26). Both eicosane ($C_{20}H_{42}$) and octacosane ($C_{28}H_{58}$) are unbranched alkanes. Furthermore, WOLFMEIER teaches that paraffin waxes are typically composed of straight chain alkanes which are unbranched hydrocarbons (Sec. 4.2.1., page 25).

18. In regard to claim 9, BLOCH discloses that the hydrocarbon mixture may be comprised of mineral oil (col. 12, lines 27-33).

19. In regard to claim 10, BLOCH discloses a method for preventing contamination (col. 4, lines 46-53) during the processing of aqueous solutions (col. 9, line 8) in open or automated systems (col. 10, lines 24-26) comprising covering said aqueous solutions (col. 4, line 46-53 and col. 12, lines 28-33) with at least one water immiscible hydrocarbon or hydrocarbon mixture (col. 11, lines 5-22).

20. As discussed in regard to claim 1, BLOCH discloses the use of wax, which is known to be a hydrocarbon mixture, as well as mineral oil, which is a hydrocarbon

mixture (col. 11, line 9), to cover (col. 12, line 30) the aqueous solution in PCR wells and act as a vapor barrier. BLOCH discloses that the vapor barrier also acts to prevent contamination (col. 4, line 53 and col. 5, lines 7-9).

21. In regard to claim 11, BLOCH discloses that the hydrocarbon covering the aqueous solution is an unsubstituted hydrocarbon (col. 11, lines 24-26). Both eicosane ($C_{20}H_{42}$) and octacosane ($C_{28}H_{58}$) are unsubstituted hydrocarbons. Furthermore, WOLFMEIER teaches that paraffin waxes are typically composed of straight chain alkanes which are unsubstituted hydrocarbons (Sec. 4.2.1., page 25).

22. In regard to claim 12, BLOCH discloses that the hydrocarbon covering the aqueous solution is comprised of a substituted hydrocarbon (col. 11, lines 26-28). Cetyl palmitate ($C_{32}H_{64}O_2$) and pentaerythritol tetrabehenate ($C_{93}H_{180}O_8$) are both ester functionalized hydrocarbons. Furthermore, WOLFMEIER discloses that many natural waxes are composed of hydrocarbons substituted with other ester groups, substituted with hydroxyl groups, or substituted with carboxylic acid groups (sec. 2.1, pages 9 and 12).

23. In regard to claim 13, BLOCH discloses that the hydrocarbon covering the aqueous solution is comprised of a saturated or unsaturated cyclic hydrocarbon. It is well known in the art that waxes are comprised of mixtures of non-cyclic and cyclic hydrocarbons. For example, WOLFMEIER discloses that paraffin waxes may contain 30 to 60% of isoparaffins and cycloparaffins. (Sec. 4.2.1., page 25).

24. In regard to claim 14, BLOCH discloses that the hydrocarbon covering the aqueous solution is comprised of a branched or unbranched acyclic hydrocarbon (col.

11, lines 24-26). Both eicosane ($C_{20}H_{42}$) and octacosane ($C_{28}H_{58}$) are unbranched acyclic hydrocarbons. Furthermore, it is well known in the art that waxes are comprised of mixtures of branched or unbranched acyclic hydrocarbon. For example, WOLFMEIER discloses that paraffin waxes may contain 30 to 60% of isoparaffins and cycloparaffins. (Sec. 4.2.1., page 25).

25. In regard to claim 15, BLOCH discloses that the hydrocarbon covering the aqueous solution is comprised of from 5 to 20 carbon atoms (col. 11, lines 24-26). Eicosane ($C_{20}H_{42}$) is a hydrocarbon comprised of 20 carbon atoms. Furthermore, WOLFMEIER teaches that paraffin waxes, according to the European Wax Federation, are typically composed of straight chain alkanes which contain 18 to 45 carbon atoms. (Sec. 4.2.1., page 25).

26. In regard to claim 16, BLOCH discloses that the hydrocarbon covering the aqueous solution is comprised of a branched or unbranched alkane (col. 11, lines 24-26). Both eicosane ($C_{20}H_{42}$) and octacosane ($C_{28}H_{58}$) are unbranched alkanes. Furthermore, WOLFMEIER teaches that paraffin waxes are typically composed of straight chain alkanes which are unbranched hydrocarbons (Sec. 4.2.1., page 25).

27. In regard to claim 18, BLOCH discloses that the hydrocarbon covering the aqueous solution mixture may be comprised of mineral oil (col. 12, lines 27-33).

28. Thus all of the features recited in claims 1-7, 9, 10-16, and 18 are anticipated by BLOCH.

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

31. Claims 8, 17, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over BLOCH in view of Perbost, et. al. (U.S. 2002/0086327 A1), hereinafter PERBOST.

32. In regard to claim 8, BLOCH discloses a barrier for aqueous solutions in an open or automated system comprising at least one water immiscible hydrocarbon or hydrocarbon mixture. BLOCH discloses that the barrier is a contamination barrier which prevents contamination of the aqueous solution.

33. BLOCH does not appear to explicitly disclose that the contamination barrier is selected from the group consisting of octane, nonane, decane and dodecane and mixtures thereof.

34. However PERBOST discloses a method of shielding biosynthesis arrays from the surrounding environment (paragraph [0013]) by applying a non-miscible fluid (paragraph [0013]) to the array to provide a barrier to prevent moisture in the air from contacting the array (paragraph [0011]). PERBOST discloses that the non-miscible fluids are immiscible with water (paragraph [0073]). PERBOST discloses that the biosynthesis arrays are in an open or automated system (paragraph [0012]). PERBOST discloses that the non-miscible fluid for protecting the biosynthesis array from moisture is comprised of hydrocarbons selected from the group consisting of octane, nonane, decane and dodecane and mixtures thereof (rows 2, 3, 4, and 6 of Table 1).

35. Thus, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the contamination barrier of BLOCH to include the non-miscible fluid shields of PERBOST in order to provide an inert and insoluble barrier (PERBOST, paragraph [0072]) to shield biopolymers from reaction with the environment and minimize the possibility of evaporation ((PERBOST, paragraph [0068]).

36. In regard to claim 17, BLOCH discloses a method for preventing contamination during the processing of aqueous solutions in open or automated systems comprising covering said aqueous solutions with at least one water immiscible hydrocarbon or hydrocarbon mixture.

37. BLOCH does not appear to explicitly disclose that water immiscible hydrocarbon or hydrocarbon mixture is selected from the group consisting of octane, nonane, decane and dodecane and mixtures thereof.

38. However, as discussed in regard to claim 8, PERBOST discloses a method of shielding biosynthesis arrays using water immiscible hydrocarbon or hydrocarbon mixture selected from the group consisting of octane, nonane, decane and dodecane and mixtures thereof (rows 2, 3, 4, and 6 of Table 1).

39. In regard to claims 19-21 and 22-24, PERBOST discloses that the hydrocarbon is comprised of from 5 to 20 carbon atoms (rows 1-11 of Table 1), of from 6 to 16 carbon atoms (rows 1-10 of Table 1), and of from 8 to 12 carbon atoms (rows 2-5 of Table 1).

Conclusion

40. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Crocker, et. al. ("Perfecting the PCR" in The Science of Laboratory Diagnosis, Isis Medical Media, Ltd., 1998, p. 521) discloses the use of mineral oil to cover aqueous PCR mixtures in order to prevent cross-contamination of PCR samples.
- b. Doolan (Malaria Methods and Protocols, Humana Press (2002), page 113, paragraph 12) discloses that a mineral oil layer is used in automatic PCR thermal cyclers in order to significantly reduce the risk of aerosol contamination.
- c. Arnold (U.S. 5,576,197) discloses a hydrocarbon barrier layer which seals aqueous PCR mixtures in order to prevent evaporation and contamination.

d. Kosak, et. al. (U.S. 5,968,729), discloses a hydrocarbon barrier layer which seals aqueous PCR mixtures in order to prevent evaporation and contamination.

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY ETHERTON whose telephone number is (571) 270-5478. The examiner can normally be reached on Monday through Friday, 7:30 a.m. to 5:00 p.m. EST, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara Gilliam can be reached on (571) 272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRADLEY ETHERTON/
Examiner, Art Unit 4171

/Barbara L. Gilliam/
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